IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION Defendant.	Case No. 2:07-cv-00001 (Hon. Jose L. Linares) (Hon. Joseph. A. Dickson) *Document Filed Electronically*

DEFENDANT'S BRIEF SHOWING CAUSE WHY IT SHOULD NOT BE HELD IN CIVIL CONTEMPT

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INTRODUCTION

The government's contempt motion is premised on a novel legal standard that is irreconcilable with Congress's statute, the agency's guidance, and over 20 years of practice in the dietary supplement industry. Under this test, Bayer must conduct *drug-level* randomized clinical trials to substantiate ordinary dietary supplement claims. *See* Dkt. No. 4 Attachment 1 at 16[1]; *see also, e.g.*, Laine Tr.[2] 55:7-55:11; Laine Tr. 128:8-10; Laine Tr. 229:14-21; Laine Tr. 56:9-12 (acknowledging test applies equally to supplements and drugs with only "subtle" differences). These clinical trials must satisfy *all* of the government's numerous criteria, or else they are deemed inadequate. *See, e.g.*, Laine Tr. at 29:16-30:1.

For over twenty years, however, Congress and the Federal Trade Commission ("FTC") have made clear that supplements are not regulated like drugs and that other types of evidence can generally be considered in substantiating dietary supplement claims. *See* Dietary Supplement Health & Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21

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[1] Specifically, the government is requiring "human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the population at which the claims are directed; and (4) use validated methods and appropriate statistical methods to assess 'outcomes.'" *Id.*

[2] A true and accurate transcript of Dr. Loren Laine's deposition taken on September 14, 2014 is attached as Exhibit A to the Certification of Timothy I. Duffy (hereinafter "Duffy Cert."). Citations to this transcript are indicated by "Laine Tr." followed by the page and line number.

U.S.C.); FTC, *Dietary Supplements: An Advertising Guide for Industry* 3 (Apr. 2001), *available at* http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry/ ("FTC Guidance"). Clinical trials are not necessary, and even animal and *in vitro* studies can be considered. *Id.* at 10. To this day, the agency has never repudiated this guidance, and the industry continues to rely on it.

If the government's new test became the law, there would be very little left of the industry. None of Bayer's competitors has conducted clinical trials meeting the government's new test, and they all make similar claims about their probiotics. Indeed, the government could not identify a single supplement of *any* kind that meets this test, *see* Government Response to Interrogatory No. 4 (Duffy Cert. Exhibit H), even though it supposedly applies to other supplements as well, *see* Laine Tr. 229:15-21 (asserting his study design is "the standard way to do clinical research," regardless of "[w]hether it is GI or some other field" and "[w]hether it is dietary supplements or drugs"); *see also* Merenstein Dec. (Duffy Cert. Exhibit C) at 11 (concluding the test "would likely require nearly all supplement advertising to be eliminated").

Nonetheless, the government has sought to impose this new standard based on the opinion of a single gastroenterologist, Dr. Loren Laine, whose identity and report were not disclosed until the filing of the complaint. Citing this report, the government has argued that drug-level clinical trials are required because that is what "gastroenterologists," the purported "experts in the field," demand. Dkt. No. 38 at 3,

10. The government's case rests on this assertion about what gastroenterologists demand.

The government's own gastroenterologist, however, refutes this assertion. In his deposition, Dr. Laine admitted he does require clinical trials of any kind, let alone drug-level clinical trials, when he treats his patients. *See* Laine Tr. 153:11-16; Laine Tr. 153:1-6; Laine Tr. 171:18-21. He likewise admitted that other gastroenterologists and other "doctors in the field" do not demand clinical trials when practicing medicine or recommending probiotics. Laine Tr. 158:15-20. Dr. Laine and his colleagues even prescribe drugs without clinical trials, even when those drugs can have "a lot of side effects." Laine Tr. 140:17-141:6. Only a "small proportion" of Dr. Laine's and his colleague's treatment decisions are made with drug-level clinical trials. Laine Tr. 79:12-19. Dr. Laine simply does not practice what he preached.

Bayer's experts agree with Dr. Laine that clinical trials are unnecessary. They too do not require drug-level clinical trials when practicing medicine, including recommending probiotic supplements and prescribing drugs. If they did require such evidence of efficacy, they could not effectively treat the large majority of their patients. The government's previously undisclosed standard is inconsistent with what "experts in the field" demand, and must be rejected.

Even if the test were legally defensible, this standard cannot be the basis for a contempt action. Contempt requires a violation of a "*clear and unambiguous* provision of the consent decree." *Harris v. City of Phila.,* 47 F.3d 1342, 1348, 1350 (3d Cir. 1995)

(emphasis added). Where, as here, the government's contempt motion depends on a legal standard found nowhere in the consent decree, there can be no contempt. The Court should reject the government's unfounded efforts to sanction Bayer for lawful conduct that is consistent with what everyone else in the industry is doing.

* * *

This is not the first time the FTC has improperly sought to change the law through a contempt action. Recently, two other district courts have rejected the government's improper attempts to impose standards not found in consent decrees. *See FTC v. Garden of Life*, 845 F. Supp. 2d 1328, 1335 (S.D. Fla. 2012), *aff'd in part and vacated in part,* 516 F. App'x. 852 (11th Cir. 2013); *see also Basic Research v. FTC*, No. 2:09-cv-0779 (D. Utah) (Nov. 25, 2014) (Duffy Cert. Exhibit F). As these courts recognized, when a consent decree speaks only of "competent and reliable scientific evidence," the government cannot redefine it through expert testimony or otherwise. *See Garden of Life*, 845 F. Supp. 2d at 1335-37; *see also Basic Research*, No. 2:09-cv-0779 at 26-27 (rejecting "Gold Standard" clinical trials). "The FTC plays an important role of ensuring that advertising claims are adequately supported so that consumers may have confidence in a product. Implicit in that role, however, is the expectation of reasonableness." *Basic Research*, No. 2:09-cv-0779 at 26-27. By "requir[ing] a level of substantiation that exceeds the requirements of the [consent decree]," *id.* at 27, the government has once again failed that most basic of expectations.

BACKGROUND

I. Statutory and Regulatory Background

As previously discussed, dietary supplements are not regulated like drugs. *See* Dkt. No. 23 at 2-3. Recognizing the health benefits and extremely low safety concerns of dietary supplements, Congress rejected attempts to subject supplements to the same legal requirements imposed on drugs. *See* DSHEA. Whereas new drugs must be pre-approved by the Food and Drug Administration, *see* 21 U.S.C. § 331(d); *id.* § 355(a), and traditionally must be supported by rigorous randomized, placebo-controlled, double-blind clinical trials, *see* 21 C.F.R. § 314.126,[3] dietary supplements need not. As long as the supplement is not marketed as a drug—*i.e.*, it is "not claim[ed] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," 21 U.S.C. § 343(r)(6); *id.* § 343(r)(6)(C) (requiring disclaimer)—it is not regulated like a drug.

Unlike drugs, the only substantiation requirement for ordinary dietary supplement claims, referred to as "structure-function"[4] claims, is that they must be

[3] *See also* FDA, *FDA's Drug Review Process*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last updated Nov 26, 2014).

[4] DSHEA defines structure/function claims as those which "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." 21 U.S.C. § 343(r)(6)(A). The FDA's final rule confirms that the claims at issue are structure/function claims. *See* 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000) ("a claim that a product 'helps promote digestion' would be a structure/function claim because it does not refer explicitly or implicitly to

"truthful and not misleading." 21 U.S.C. § 343(r)(6)(B); *see also id.* § 321(ff) (defining "dietary supplement" as any non-tobacco product "intended to supplement the diet"). This is a "lesser standard" than the requirement for drugs. *Dietary Supplements: Hearing before the H. Subcomm. on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations*, 103rd Cong. 27 (statement of Sen. Hatch); *Regulation of Dietary Supplements: Hearing Before the H. Subcomm. on Health and the Environment of the Comm. on Energy and Commerce*, 103rd Cong. 8 (statement of Rep. Gallegly) (supplement claims may be made if "there exists a reasonable scientific basis" for the claims).

Consistent with Congress's intent, the FTC has long recognized—and never denied—that the substantiation standard for dietary supplements is lower and more "flexible" than the drug standard. Over 13 years ago, the agency issued industry guidance which stated that dietary supplement claims need only be supported by "competent and reliable scientific evidence." *See* FTC Guidance at 3; *see also* FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)*

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an effect on a disease state"); *id.* at 1026 ("for relief of 'occasional constipation' should not be considered [a] disease claim[]"); *id.* at 1031 (stating that "'[a]lleviates the symptoms referred to as gas'" and "'alleviates bloating'" are structure/function claims "because the symptoms . . . are not sufficiently characteristic of specific diseases"); *see also id.* at 1033 ("'helps maintain regularity' is an acceptable structure/function claim"); *see also id.* at 1015, 1029. The government does not dispute that these claims at issue are structure/function claims. Dkt. No. 4 Attachment 1 at 21-22; *see also* Laine Tr. 209:14; *id.* § 343(r)(6)(A) (identifying types of permissible dietary supplement claims, including structure/function claims).

(6) of the Federal Food, Drug, and Cosmetic Act (Dec. 2008) ("FDA Guidance"). The FTC defined this term of art to mean: "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." FTC Guidance at 9.

The guidance makes clear that this standard is *not* the drug standard. FTC Guidance at 9-18. Instead, "competent and reliable scientific evidence" is a "*flexible*" standard, and "[t]here is *no fixed formula* for the number or type of studies required." *Id.* at 8-9 (emphasis added). Although "well-controlled human clinical studies are the most reliable form of evidence[,]" they are not necessary, and other types of evidence are often considered, including:

- Other human studies
- Animal studies
- In vitro studies
- Epidemiological evidence

See id. at 10 ("Results obtained in animal and *in vitro* studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible."); *id.* ("When a clinical trial is not possible (e.g., in the case of a relationship between a nutrient and a condition that may

take decades to develop), epidemiologic evidence may be an acceptable substitute . . . especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect.").

Equally importantly, studies on the precise formula used in the advertised product are not required, and it can be "*appropriate to extrapolate* from the research to the claimed effect," even if there "are significant discrepancies between the research conditions and the real life use being promoted." *Id.* at 16 (emphasis added); *see also id.* ("advertisers need to evaluate whether it is appropriate"). The "standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science." *Id.* at 8. "There is *no set protocol* for how to conduct research that will be acceptable under the FTC substantiation doctrine." *Id.* at 12 (emphasis added). The FDA agrees in its guidance, recognizing that randomized, controlled clinical trials for dietary supplements may not be "possible, practical, or ethical." *See* FDA Guidance at 6.

Consistent with this standard, Bayer is required to possess "competent and reliable scientific evidence" for its dietary supplement claims. Dkt. No. 2 at 2. The consent decree it signed in 2007 requires such evidence—and only such evidence. As the government admits, the decree standard is word-for-word identical (with the exception of a typographical error) to the one in the guidance for the rest of the industry. Amended Response to Request for Admission No. 1 (Duffy Cert. Exhibit

G) (noting that the FTC Guidance uses the word "have" while the Consent Decree uses the word "has").

Significantly, Bayer's consent decree does not contain any provision requiring clinical trials of any kind, let alone drug-level clinical trials. *Other* consent decrees that the FTC has entered into with *other* companies for *other* types of products require clinical trials (though not drug-level trials) for *other* claims. *See e.g., FTC v. Iovate Health Sci. USA*, Consent Decree at 7, No. 10-CV-587 (W.D.N.Y. July 29, 2010); *United States v. Jason Pharm., Inc.,* Consent Decree at 3, 6, No. 12-CV-01476 (D.D.C. Sept. 17, 2012). But Bayer's decree does not include any such requirement.

II. Product Background: Phillips' Colon Health

Among the dietary supplements Bayer sells is Phillips' Colon Health ("PCH"), a probiotic supplement that supports digestive health and makes standard claims similar to those made by the rest of the industry. Merenstein Dec. at 11. Probiotics are microorganisms that provide health benefits, such as supporting a healthy digestive system. The benefits of probiotics have been well-recognized for over 100 years, and there is no dispute that probiotics are safe. *See* Dkt. No. 4 Attachment 1 at 9 n.4 ("government is not challenging the safety of [PCH]"); Laine Tr. 192:1 ("I was not suggesting that PCH was unsafe."). Many of us consume probiotics on a regular basis. Probiotics can be purchased in yogurt, milk, and other dairy products, as well as granola bars, juices, chocolate, and scores of supplements.

The science supporting the efficacy of probiotics in general and PCH in particular is substantial. Bayer's scientific evidence includes, among other studies and research: Numerous randomized clinical trials (though not drug-level trials, as required by Dr. Laine, *see* Laine Dec. at 17-18) on the species of bacteria in PCH;[5] *in vitro* and animal studies on the particular strains in the product; and sophisticated genomic testing confirming that all of the bacterial strains include metabolic pathways supporting digestive health.

III. Procedural History

Bayer has been marketing PCH since 2008 and has notified FDA of each of its label claims. Three years later, in August 2011, the FTC began to investigate whether Bayer possessed adequate substantiation for PCH. At no time during the course of the entire investigation, did the FTC assert the drug-level clinical standard the government is now espousing.

A year and a half later, in March 2013, the FTC referred the case to the Department of Justice for enforcement. On September 12, 2014, the government filed its motion for an order to show cause, announcing for the first time its drug-level requirement. Dkt. No. 4. After the Court issued the order, Bayer sought discovery

[5]Probiotics, like all bacteria, are formally categorized into taxonomic groups of class, order, family, and genus. Species within a particular genus are further defined by a distinct combination of traits, meaning strains within one species share this combination. *See generally*, Erko Stackebrandt, et al., *Report Of The Ad Hoc Committee For The Re-Evaluation of The Species Definition in Bacteriology*, 52 Int'l. Journal of Systematic & Evolutionary Microbiology 1043, 1044 (2012).

from the government to inquire about this novel standard for supplements. The government opposed discovery, including a deposition of its purported expert, Dr. Laine. Dkt. No. 60. Judge Dickson, however, required the government to respond and allowed Bayer to depose Dr. Laine, Dkt. No. 63.

IV. Dr. Laine's Testimony

It soon became clear why the government did not want Dr. Laine to be deposed. In his deposition, he conceded that he is not an expert in probiotics. Laine Tr. 283:15-16; *see also* Laine Tr. 381:3-382:21. He also admitted that, when practicing medicine, gastroenterologists do *not* require randomized clinical trials ("RCTs") of any kind, let alone the "high quality" drug-level trials he discusses in his declaration. *See e.g.,* Laine Tr. 152:17-153:6; Laine Tr. 153:17-21 (affirming that "when you're in the field treating your patients, sometimes you have RCTs, and sometimes you don't."); Laine Tr. 158:9-20.

Gastroenterologists do not even require clinical trials when prescribing drugs.[6] Laine Tr. 153:13-16 ("not having" a study that meets my "specific study design" . . . "would not prevent me from prescribing a drug in my practice."); *see also* Laine Tr. 133:20-134:3 (agreeing that doctors "prescribe some drug[s] without RCTs"); Laine

[6] The FDA generally requires clinical trials to approve a drug. *See* 21 U.S.C. § 355. When the FDA approves a drug, it does so for a particular purpose, which is indicated on the label. *Id.* § 355(b)(1)(F). Physicians, however, can prescribe drugs for other purposes, which may not be substantiated by a clinical trial. *See* FDA, *Off-Label and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet*, *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.

Tr. 171:8-10. In "only a minority of cases," do gastroenterologists have clinical trials supporting their patient decisions, ranging from prescribing drugs, to recommending supplements, to performing surgery. Laine Tr. 73:11-13; *see also* Laine Tr. 79:12-80:1 ("high-quality evidence" for only a "small proportion" of decisions). Laine is content just "know[ing] that there is evidence" even if he does not know "whether it's high quality or moderate quality." Laine Tr. 136:13-15. The same is true, he said, for other physicians, such as internists and primary care physicians, *see* Laine Tr. 132:14-133:15, who probably see more patients with mild gastrointestinal symptoms than gastroenterologists do. Laine Tr. 357:1-3 ("they would go to their primary care first for occasional symptoms that were not severe").

Nonetheless, Dr. Laine asserts that, as a matter of *clinical research*, drug-level clinical trials are necessary. *See, e.g.,* Laine Tr. 54:18-55:11 ("I developed a test that I think everybody would agree who does clinical research," and the test would apply to "any situation"); Laine Tr. 56:9-12; Laine Tr. 128:8-10. Although gastroenterologists and other physicians do not require these clinical trials for treating patients or practicing medicine, he claims that clinical researchers require his study design for testing products. Laine Tr. 153:4-6 ("[M]y study design here has nothing to do with whether I would choose to treat the patient or not."). According to Dr. Laine, this standard applies equally to "drugs" and dietary "supplements," *see, e.g.,* Laine Tr. 127:22-128:14; *see also* Laine Tr. 54:18-55:8; Laine Tr. 229:15-21 (regardless of whether the products are "dietary supplements or drugs"), and its principles apply to products

in other areas of research, *see* Laine Tr. 128:15-16 (claiming the test is not "unique to GIs"); Laine Tr. 128:21-22 ("[T]his would be a general rule. It's not GI-based."), including rheumatology, ophthalmology, and physical therapy, *see* Laine Tr. 129:15-16, 131:16-17.

ARGUMENT

I. The government's attempt to require drug-level clinical trials is invalid. By eliding the distinction between drugs and dietary supplements, the government is disregarding DSHEA, the FTC's own guidance, and the terms of Bayer's consent decree. These authorities have long established that dietary supplement manufacturers can rely on studies that are not drug-level clinical trials—including animal studies, in vitro studies, human observation studies, and clinical trials that do not meet the FDA's standard for approving new drugs.

The FTC has never publicly repudiated this standard, revoked its guidance, or engaged in notice-and-comment rulemaking. Nonetheless, dissatisfied with the existing standard, the FTC has sought to strong-arm companies into accepting requirements that go beyond what the law requires. As two district courts have recently held, this is unreasonable and unlawful. If the FTC wants to change the standard, it must try to do so though proper legal channels. It cannot threaten contempt and demand "Gold Standard" clinical trials through *ipse dixit* and a single expert.

But, even if the government could require drug-level clinical trials by finding an expert willing to agree with it, it cannot do so here, because the purported expert undermined the government's position. According to the government, "gastroenterology is the directly relevant area of expertise." Dkt. 1 at 16; Dkt. No. 38 at 3. This is the premise of the government's contempt motion. In his deposition, however, Dr. Laine admitted that gastroenterologists and other "doctors in the field" do not require clinical trials, let alone drug-level clinical trials, when recommending supplements, prescribing drugs, or making any number of patient decisions. Laine Tr. 153:17-21. Bayer's gastroenterologist, Dr. Brian Fennerty, fully agrees, as does Dr. Daniel Merenstein, a primary care physician and probiotics expert who regularly treats patients with the "specific discomforts" and "digestive symptoms" at issue. "Experts in the field" reject the government's novel position.

Well aware that gastroenterologists do not require clinical trials meeting the government's test, Dr. Laine sought to defend the test on alternative grounds never asserted by the government. Dr. Laine argued that, although gastroenterologists do not require clinical trials, "clinical researchers" do. This position is meritless. First, it contradicts the government's position on who the relevant experts are. Second, if clinical researchers who demand drug-level clinical trials for "any situation," Laine Tr. 54:20-55:15; *see also id.* Laine Tr. 128:15-16, could be deemed the relevant experts, there would be nothing left of DSHEA; in "any situation," clinical drug trials could be required for dietary supplements. Third, clinical drug trials are highly impractical,

potentially unethical, and widely rejected by researchers who, unlike Laine, have actually done research on dietary supplements and probiotics in particular.

II. In any event, even if the government's test were legally defensible, Bayer cannot be held in contempt for violating a standard that did not previously exist. To be "placed at risk of contempt," a defendant must have been "given specific notice of the norm to which [it] must pattern [its] conduct," and must have violated "clear and unambiguous provision of the consent decree." *Harris v. City of Phila.,* 47 F.3d at 1348, 1349 (3d Cir. 1995). Because the government's novel test is found nowhere within the "four corners" of the consent decree, *Harris v. City of Phila.*, 137 F.3d 209, 212 (3d Cir. 1998), and is disputed by many experts, Bayer cannot be held in contempt.

The government's discovery responses confirm that its drug-level study design is not clear and unambiguous. The government never before publicly asserted that the probiotic claims at issue—which virtually all of Bayer's competitors make—require drug-level clinical trials. Nor had the government previously said that ordinary dietary supplement "structure/function" claims require drug-level clinical trials, even though Dr. Laine admitted that his test would have to apply to them too. The government's standard is novel and cannot support a contempt action.

I. The Government Is Applying An Erroneous And Unjustifiable Legal Standard.

A. The Government's Position Is Inconsistent With Applicable Law, Including DSHEA, Agency Guidance, The Consent Decree, And The First Amendment.

The government's standard is contrary to law. The Court should reject the government's attempt to require drug-level clinical trials for ordinary dietary supplement claims.

First, Congress expressly intended to treat dietary supplements differently from drugs. That was the whole point of enacting DSHEA. *See, e.g.*, *Dietary Supplements: Hearing before the H. Subcomm. on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations*, 103rd Cong. 27 (1993) (statement of Sen. Hatch) ("[I]f you can show scientific evidence that justifies the formulation then it would be all right. *It would be a lesser standard.*") (emphasis added); *Regulation of Dietary Supplements: Hearing Before the H. Subcomm. on Health and the Environment of the Comm. on Energy and Commerce*, 103rd Cong. 8 (1993) (statement of Rep. Gallegly) (supplement claims may be made if "there exists a reasonable scientific basis" for the claims).

Congress's reasons for doing this were clear. It explicitly found on the face of the statue that "the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies." DSHEA, § 2(1)-(2). Congress also found that "dietary supplements are safe within a broad range of

intake, and safety problems with the supplements are relatively rare." *Id.* § 2(14). Congress thus believed that "consumers should be empowered to make choices" about dietary supplements," *id.* § 2(8); that "the Federal Government should not take any actions to impose unreasonable regulatory barriers," *id.* § 2(13); and that "legislative action that protects the right of access to consumers to safe dietary supplements is necessary in order to promote wellness," *id.* § 2(15)(A).

Consistent with these findings, Congress reduced the regulatory burdens on dietary supplements. The government could no longer treat dietary supplements like drugs and demand drug-standard RCTs. Instead, the manufacturer need only have substantiation that its claims are "truthful and not misleading." *Id.* § 6.

By disregarding DSHEA and requiring full-fledged RCTs, the government is trying to do precisely what Congress sought to prevent. The government is asking this Court to impose on probiotic supplements all of FDA's regulatory criteria for clinical drug trials. *See* Laine Tr. 39:1-49:22 (noting that FDA's first criteria, that the study have a clear statement of its objective, is implicit; and that the rest of the criteria are explicit in his test); *compare* 21 C.F.R. § 314.126(b)(1)-(7) *with* Laine Dec. at 6-16.[7]

[7] Dr. Laine did assert that the FDA criteria required an "interim analysis," whereas his study design does not. Laine Tr. 52:7-8. However, the FDA regulation requires no such thing. *See* 21 C.F.R.§ 314.126(b)(7) (only requiring that adequate statistical methods be used *if* interim analysis is performed). Dr. Laine also asserted that the FDA required "two doses" of the study drug, Laine Tr. 52:10-13, but this is also incorrect. Two doses are necessary only if the clinical trial is using a dosage control instead of a placebo control, *see* 21 C.F.R. § 314.126(b)(2)(ii); Dr. Laine does not even give companies the option of using alternative controls.

The government also wants to impose additional criteria that are not included in FDA's regulation. *See id.*; Laine Tr. 49:9-51:22 (admitting that the regulation does not require double-blinding and it permits types of controls other than a placebo-control).

This is contrary to DSHEA and Congress's intent in enacting the statute. If the government could require drug-level trials for dietary supplements simply by proffering an expert, the statute is next to worthless. Dietary supplements could be subject to the drug standard (and beyond), notwithstanding Congress's intent.

Second, the government's position conflicts with agency guidance. Consistent with DSHEA, the FTC's published guidance states that the substantiation standard for dietary supplements is "sufficiently flexible to ensure that consumers have access to information about emerging areas of science." FTC Guidance at 8. To be sure, "well-controlled human clinical studies are the most reliable form of evidence." *Id.* at 10. But "[r]esults obtained in animal and in vitro studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible." *Id.* (emphasis added). Extrapolation may also be appropriate, even when there "are significant discrepancies between the research conditions and the real life use being promoted." *Id.* at 16 (emphasis added); *see also id.* ("advertisers need to evaluate whether it is appropriate"). There is "no fixed formula," *id.* at 9, and "no set protocol for how to conduct research that will be acceptable," *id.* at 12; *supra* at 6-8.

Contrary to the government's suggestion, *see* Dkt. No. 38 at 1-3, the published guidance does *not* state that the substantiation standard is whatever a government-appointed expert says it is. It is especially inappropriate to rely on such an expert when he admits he does not even know or understand the regulatory regime. Dr. Laine had never heard of DSHEA before his deposition, Laine Tr. 182:20-183:3, had never read the agency guidance before he wrote his declaration, Laine Tr. 234:9-13, and had never made any effort to ensure that his standard complied with the regulations or law, Laine Tr. 196:12-17. In his view, they were completely irrelevant. Laine Tr. 195:2-3 ("I'm not paying attention to the regulations or law."). In no circumstance would they affect his view of what substantiation is required. Laine Tr. 194:19-195:2.

Third, the government's test is inconsistent with the terms of Bayer's consent decree, which does not require randomized clinical trials, let alone drug-level trials. The FTC has signed *other* decrees with *other* companies that expressly require randomized clinical trials (though not with all the requirements Dr. Laine would impose). *See supra* at 9. Bayer's decree omits this language.

Confronted with similar facts, two district courts recently rejected the FTC's attempt "to read additional requirements into the Consent Decree." *Garden of Life*, 845 F. Supp. 2d at 1335; *see also Basic Research*, No. 2:09-cv-0779. When a consent decree speaks only of "competent and reliable scientific evidence," the government cannot retroactively redefine it through expert testimony or otherwise. *See Garden of*

Life, 845 F. Supp. 2d at 1335-37. As one court put it, in rejecting the FTC's attempt to require "Gold Standard" clinical trials:

> The FTC plays an important role of ensuring that advertising claims are adequately supported so that consumers may have confidence in a product. *Implicit in that role, however, is the expectation of reasonableness.* Here, the approach taken by the FTC through its expert requires a level of substantiation that exceeds the requirements of the Agreement and the court's June 2012 Order.

Basic Research, No 2:09-cv-0779 at 26-27 (emphasis added).

Once again, the agency has disregarded this "expectation of reasonableness." Like the courts in *Basic Research* and *Garden of Life*, this Court should reject the government's attempt to disregard the terms of the consent decree and applicable law.

Fourth, requiring dietary supplement companies to satisfy the FDA's drug-approval test violates the First Amendment. Restrictions on commercial speech are subject to heightened scrutiny unless the speech is actually false or inherently misleading. *See Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976). To satisfy this heightened scrutiny, (1) "the asserted governmental interest [must be] substantial"; (2) "the regulation [must] directly advance[] the governmental interest asserted"; and (3) "it [must] not [be] more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n.*, 447 U.S. 557, 566 (1980).

Dr. Laine's deposition confirms that Bayer's claims are not false or misleading. He does not dispute that there is sufficient evidence for physicians to recommend

PCH, Laine Tr. 218:10-12 ("My report wasn't related to what goes into a doctor making a decision about treating or providing intervention."); he does not dispute that physicians recommend probiotic supplements (none of which meets Dr. Laine's test, *see* Merenstein Dec. at 11), Laine Tr. 290:7-299:22; and he does not dispute that his patients tell him that probiotic supplements work, Laine Tr. 276:17-19. He also admits it "might be true" that PCH is effective. *See* Laine Tr. 277:17-19. Dr. Laine asserts only that there should be drug-level clinical trials confirming this.

There is no "substantial" government interest in imposing a requirement of drug-level trials on supplements. To the contrary, in enacting DSHEA, Congress deliberately distinguished dietary supplements from drugs. *See* S. Rep. No. 103-410, at 2 (1994) ("The purpose of this legislation . . . is also to clarify that dietary supplements are not drugs . . . ."). Congress established "a more lenient standard for dietary supplements," 136 Cong. Rec. S16611 (daily ed. Oct. 24, 1990) (Statement of Sen. Hatch) Nutrition Labeling Health and Education Act of 1990, precisely to promote "the dissemination of more truthful and non-misleading information." 65 Fed. Reg. at 1003; *see also* FTC Staff Comments, *In re Request for Comment on First Amendment Issues* at 22 (2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf ("FTC Comments"). Congress decided that drug-level trials were not necessary to substantiate dietary supplement claims. The Court should reject the government's unconstitutional test.

B. Gastroenterologists And Other Physicians In The Field Reject The Government's Test.

The government nonetheless contends that Bayer must possess drug-level clinical trials because that is what "experts in the field demand." Dkt. No. 38 at 3; *see also id.* at 9 ("whatever substantiation experts in the field would expect"). According to the government, in this case, the relevant experts are "gastroenterolog[ists]," because the "specific discomforts" at issue "are digestive symptoms." Dkt. No. 4 Attachment 1 at 16; *see also* Dkt. No. 38 at 10 ("In keeping with the 2001 FTC guidance, the relevant area to evaluate claims of constipation, diarrhea, and gas and bloating is gastroenterology."); Government Response to Interrogatories Nos. 1-4 (repeatedly relying on "Loren Laine, an eminent professional in *the relevant area (gastroenterology)*") (emphasis added). This is the premise of the government's contempt motion.

But gastroenterologists uniformly reject the government's test. Even Dr. Laine admits that gastroenterologists and other "doctors in the field" do not require clinical trials when practicing medicine. Laine Tr. 158:12-20. Physicians recommend supplements, prescribe drugs, and perform surgery without clinical trials. Laine Tr. Laine Tr. 132:20-133:15. Dr. Laine has clinical trials only a "small proportion" of the time. Laine Tr. 79:12-14; Laine Tr. 73:11-14 ("good evidence is available to guide clinical decisions in only a minority of cases"); Laine Tr. 72:4-7 ("[W]e can all agree

that it's common . . . in practice that we do not have high-quality evidence for things we often do."); Laine Tr. 164:3-9 (agreeing it would not be appropriate for a gastroenterologist to limit himself to "high-quality RCTs," because "[y]ou, again, look at everything"). Even for the occasional symptoms at issue in this case, Dr. Laine recommends a supplement (fiber or psyllium), without any clinical trials in a healthy population that meet his test. Laine Tr. 172:16-173-10; *see also* Merenstein Dec. at 12.

Dr. Laine also did not dispute that gastroenterologists often recommend probiotics to their patients or that probiotics work. Laine Tr. 282:15-19. Although he does not affirmatively recommend probiotics, some of his patients take probiotics. Laine Tr. 270:19-22. He is "definitely . . . fine" with them taking probiotics, and tells them "that's okay." Laine Tr. 270:22-271:1. Some of these patients report to him that the probiotics worked for "*all* [of] the symptoms" at issue. Laine Tr. 276:14-19 (emphasis added). Laine does not dispute his patients' claims.

Bayer has retained a leading gastroenterologist, Dr. Brian Fennerty,[8] who agrees that in the field of gastroenterology clinical trials are unnecessary to show efficacy of probiotics. *See* Fennerty Dec. at 3-7. He too regularly prescribes drugs and makes other treatment decisions without clinical trials. *See id.* He also "recommend[s]

[8] Dr. Brian Fennerty has published more than 300 peer-reviewed papers in leading medicial journals including the *New England Journal of Medicine*, and *Annals of Internal Medicine*. Dr. Fennerty has served on the FDA's Gastroenterology and Urology Devices Advisory Panel, American Board of Internal Medicine's Gastroenterology Committee, and is a past president of the American Society for Gastrointestinal Endoscopy. Fennerty Dec. at 1-2; *id.* at Appendix A (Duffy Cert. Exhibit B).

probiotics, including PCH, to [his] patients who experience" the digestive symptoms at issue. *Id.* at 4; *see also id.* at 9 ("Gastroenterologists Agree that Probiotics Offer Benefits to Large Patient Base").

Dr. Fennerty is aware that *none* of these probiotic supplements has drug-level clinical trials satisfying the government's test, but nevertheless recommends probiotics. *Id.* at 4-5. Although drug-level clinical trials are the highest level of evidence, gastroenterologists do not have such evidence when they make the "large majority" of patient decisions. *Id.* at 3-4. Thus "gastroenterologists and other physicians do frequently consider other types of 'tests, analyses, [and] research studies,' including biological plausibility, animal studies, open-label studies, *in vitro* studies, expert guidance, and clinical practice results," as well as clinical trials that do not meet the government's study design. *Id.* at 4-5.

Dr. Daniel Merenstein,[9] a primary care physician and probiotics expert, agrees with the gastroenterologists. Like Dr. Laine and Dr. Fennerty, Dr. Merenstein treats the "specific discomforts" and "digestive symptoms" at issue. As a primary care physician, he likely sees more patients with these symptoms than does a gastroenterologist. Laine Tr. 349:14-18.

[9] Dr. Merenstein is a professor of medicine at Georgetown University where he sees patients, lectures, and performs clinical research. Merenstein Dec. at 1-3. (Duffy Cert. Exhibit C). Dr. Merenstein has been the lead investigator in numerous probiotic clinical trials and recently was one of the authors of the ISAPP expert consensus scientific report. *Id.* at 2-3.

Also like Dr. Laine and Dr. Fennerty, Dr. Merenstein regularly makes treatment decisions without drug-level clinical trials. *See* Merenstein Dec. at 5-10. Among other things, he prescribes drugs and recommends supplements without drug-level trials. *See id.*; *see also id.* at 6 ("Physicians practicing medicine rely on the totality of scientific evidence from many types of studies, not just drug-level clinical trials prescribed by Dr. Laine."). Most relevant here, he "ha[s] recommended PCH to [his] patients" who have the symptoms at issue "and will continue to do so." *Id.* at 14. He believes that Bayer's claims are substantiated and that PCH "can effectively help individuals who are generally healthy but suffer from constipation, diarrhea, gas and bloating." *Id.* at 14-16.

Dr. Merenstein explains that "probiotics should not be held to a higher standard of evidence than other foods or supplements," which are not subject to a drug standard. Merenstein Dec. at 7. If they were, common vitamins would have to be pulled from shelves. For instance, "there are no robust RCTs showing that Vitamin C improves the immune system in healthy children." *Id.* at 11. The expert consensus report by the International Scientific Association for Probiotics and Prebiotics ("ISAPP")—of which Dr. Merenstein was an author—expresses this same view. *See* Colin Hill *et al.*, *The International Scientific Association for Probiotics and Prebiotics Consensus Statement on the Scope and Appropriate Use of the Term Probiotic*, 11 Nature Reviews Gastroenterology & Hepatology 506, 607 (2014) ("ISAPP Consensus Report"); *see also id.* at 508 (concluding that "certain effects can be ascribed to

probiotics as a general class" at the species level for the three species of bacteria in PCH, including the gastrointestinal benefit of "supporting a healthy digestive tract.").[10]

Finally, Dr. Merenstein concludes that, as best he can tell, no probiotic meets Dr. Laine's standard. *See* Merenstein Dec. at 11. Dr. Merenstein analyzed the published scientific support for four of the best studied and widely recommended probiotics on the market. He determined that "[e]ach of these probiotic products makes claims similar to those made for PCH," and none "meet[s] Dr. Laine's standard." *Id.* at 11. Thus, the government's test would virtually eliminate probiotics advertising. *Id.* at 11-12 (also concluding that "nearly all supplement advertising" would be "eliminated").

C. Dr. Laine's Alternative Position Should Be Rejected.

Forced to concede that gastroenterologists and other "doctors in the field" do not support the government's test, Dr. Laine attempted in his deposition to justify the test on his own terms, not the government's. According to Dr. Laine, physicians conducting "clinical research" require his study design for all fields of medicine—

[10] Dr. Merenstein makes clear that the government's reply brief misrepresents the ISAPP Consensus Report. According to the government, the ISAPP Consensus Report "specifies" that "strain-specific RCTs" are the "[m]inimum level of evidence" required for the claims at issue, and that this is "exactly what Dr. Laine requires." Dkt. No. 38 at 6 n.5. To the contrary, according to Dr. Merenstein, who is one of the authors of this report: "ISAPP confirms that, directly contrary to Dr. Laine's position, experts from a variety of disciplines and countries agree that strain specificity and drug level randomized controlled trials are not required." Merenstein Dec. at 9.

including rheumatology and opthamology—and regardless of the product at issue. For drugs, dietary supplements, foods, and even educational brochures, his study design is required, with only "subtle" differences depending on context. Laine Tr. 56:7-12; *see also* Laine Tr. 229:15-21 (asserting that his study design is "the standard way to do clinical research," regardless of "[w]hether it is GI or some other field" and "[w]hether it is dietary supplements or drugs").

The proper experts, Dr. Laine argued, are "clinical researchers" who have some experience with the symptoms at issue. Such clinical researchers could be gastroenterologists, but need not be. Moreover, he insisted that not all gastroenterologists qualify as experts because they do not "have the skill sets, so to speak, to discuss clinical research in this area." Laine Tr. 360:22-361:15. To Dr. Laine, "[i]t is actually the clinical research issue, which I think is probably a larger portion of this endeavor." Laine Tr. 361:4-7.

The Court should reject Dr. Laine's attempted justification for three reasons. First, it conflicts with the government's own position that "gastroenterolog[ists]" are the relevant experts. Dkt. No. 4 Attachment 1 at 16. The government took this position because the "specific discomforts" at issue "are digestive symptoms." *Id.* And the government repeatedly asserted this position throughout the litigation—in its opening brief, its reply brief, and multiple discovery responses. *See supra* at 22. At no time did the government say that clinical researchers are the appropriate experts. It

certainly did not argue that a rheumatology researcher was potentially more relevant than a gastroenterologist seeing patients and practicing medicine.

Second, if clinical researchers demanding drug-level clinical trials could be deemed the relevant experts, there would be nothing left of DSHEA or the agency guidance, especially since Dr. Laine asserts his test applies to "any situation," Laine Tr. 54-20-55:15; *see also, e.g.*, Laine Tr. 128:15-16. Under no circumstance could a dietary supplement claim be based on animal studies, in vitro studies, genetic studies, or anything else. Dietary supplement manufacturers would need to conduct the clinical studies that Dr. Laine would require for drugs. Laine Tr. 127:22-128:14. The agency guidance states that there is "no fixed formula," FTC Guidance at 9, and "no set protocol for how to conduct research that will be acceptable," *id.* at 12; *see also id.* at 16 (permitting extrapolation); *supra* at 6-8. But, if Dr. Laine's position became the law, there would be a single, fixed formula and only one permissible protocol: drug trials.

Third, the type of test he proposes makes no sense for dietary supplements in general or probiotics in particular.[11] This should come as no surprise. Dr. Laine

[11] Dr. Laine cited one document in his deposition and two others in his expert report for the proposition that his study design was "widely accepted" in documents produced by Bayer. Laine Dec. 5-6; Laine Tr. 487:2-5 Not so. One article describes the study design needed for health claim approval under the *European* regulatory regime, and has nothing to do with supplements in the United States. FTC_PCH0014517. The second describes only one of Laine's many requirements (validated instruments) but does not speak of any others, including strain-specificity, randomization, placebo-control, double-blinding, exact end points and populations.

admitted he is not an expert in dietary supplements and has never conducted a clinical trial or other study on dietary supplements. Laine Tr. 376:4-6; Laine Tr. 382:16-383:10. He also admitted he is not a probiotics expert, even though the government presented him as an expert in a probiotics case. Laine Tr. 283:15-16 ("I wouldn't say I am an expert in probiotics, no."); Laine Tr. 299:21-22 ("I am not an expert in probiotics, nor did I claim to be."). His knowledge of probiotics is limited: He has never conducted any clinical trials or studies on probiotics, and he does not even know the two most common probiotic genera. Laine Tr. 381:6-22, 255:18-19.

Dr. Merenstein, by contrast, is an expert in probiotics who has done trials and studies on probiotics. In his view, experts in the field do not require drug-like clinical trials for dietary supplements, and "such studies are often impractical." Merenstein Dec. at 12. Because "many people consume probiotics in their normal diet," and "because we would be studying generally healthy individuals," clinical studies would require an "extremely large number of participants" and last "likely for multiple years," in order to show statistically significant results. *Id.* at 12-13; *see also* Laine Tr. 180:4 ("Well, it would have to be pretty large . . .").

FTC_PCH0014503. The third recounts a speech given by an FTC official in his *personal* capacity, not on behalf of the agency, and in any event it does not say that drug-level RCTs are required; the article also concludes that there is "[c]onfusion among stakeholders" and a need for "future discussion" on how to substantiate probiotic claims. FTC_PCH0014480.

Likewise, Jeffrey Blumberg is a nutrition and supplement expert, who, unlike Dr. Laine, has experience conducting clinical trials for dietary supplements.[12] Blumberg Dec. at 1-4. Dr. Blumberg explains that drug-level clinical trials are not required to substantiate ordinary dietary supplement structure/function claims like those at issue. Such trials may not even be "possible or feasible," *id.* at 7, and they "can lead to ethical problems" because participants in the control group may need to be limited in the amount of vitamins they could consume. *Id.* ("sufficiently low intakes of beneficial constituents are, by definition, associated with harm in some body systems and so can lead to ethical problems"); *id.* at 9 (discussing need for "an extremely large sample size or long-term study," which "further increases the expense of such trials"). "Authoritative medical and scientific bodies including the Institute of Medicine and U.S. Preventive Services Task Force agree that RCT designs are limited and potentially problematic when used for nutrition and health." *Id.* at 11.

Accordingly, experienced researchers in dietary supplements consider "the totality of several well-established research approaches, including *in vitro* experiments, animal models, population-based cohorts (observational research), and clinical trials, including but not limited to RCTs." Blumberg Dec. at 5. Dr. Blumberg's "scientific colleagues in the industry as well as colleagues in academia do not require or expect

[12] Dr. Blumberg has published more than 350 articles describing his research and studies of foods, nutrients, dietary bioactive compounds, and dietary supplements. *See* Blumberg Dec. at 2-4 (Duffy Cert. Exhibit E).

RCTs on dietary supplements." *Id.* at 13; *see also id.* at 2 (concluding that randomized, controlled trials are "not the best method by which to reveal the role of nutrients and dietary constituents in healthy people").

Moreover, "Dr. Laine's test would have far reaching implications." Blumberg Dec. at 10. "If Dr. Laine's drug-level RCT criteria became the law, it would effectively remove almost all of the existing dietary supplements with structure/function claims from the market." *Id.* at 13. It would also deter companies "from developing many other dietary supplements making structure/function claims." *Id.* at 13.

Finally, Dr. Andrew Benson is a microbiologist and geneticist who has studied the human gut microbiome for over 19 years.[13] Benson Dec. at 3-4 (Duffy Cert. Exhibit D). He explains that Dr. Laine's demand for drug-level clinical trials on PCH represents a misunderstanding of "the underlying biology of the gut microbiome and probiotic organisms." Benson Dec. at 23. Whereas Dr. Laine—who admittedly has never studied the genetics of probiotics, Laine Tr. 384:1-22, and is not an expert in probiotics, Laine Tr. 283:15-16—seeks to require strain-specific clinical trials, "[t]he core metabolic functions of the bacteria in PCH are not strain-specific." Benson Dec.

[13] Dr. Benson leads the University of Nebraska Gut Function Initiative, an internationally recognized, federal-funded research program in comparative and population genomics of bacterial species. Benson Dec. at 3-4. He has authored or co-authored over 50 publications in well-known, peer reviewed journals that describe seminal discoveries in genetics and microorganisms. *Id.*

at 6-7. Rather, "[e]ach of the strains of bacteria in PCH have a shared core of genetic content, shared with all other strains within their species, that drives their ability to impact normal gut functioning." *Id.*

Dr. Benson tested PCH and demonstrated that the probiotics in the product "contain the shared-core metabolic capabilities of their respective species and genera." Benson Dec. at 15. Because of this shared content, the effectiveness of PCH "is supported by many species-level randomized controlled trials on various digestive end points, including those related to constipation, diarrhea, gas and bloating." *Id.* at 15-16. These tests further "confirm that PCH helps with constipation, diarrhea, gas and bloating," *id.* at 15, as does the "recent [ISAPP] consensus report." *Id.* at 16, 22. As Dr. Benson concludes: "Bayer's claims are well substantiated," the government ignores "the incredible advancements in metagenetics and our understanding of the human microbiome," and "[i]f the government's position were to prevail, it would be a major step back for the scientific development of probiotics and our understanding of the gut microbiome." *Id.* at 23-24.

II. Even If The Government's New Test Were Legally Defensible, Bayer Still Cannot Be Held In Contempt.

Even if the Government's test were legally defensible, Bayer still cannot be held in contempt. First, contempt requires clear and convincing evidence of a violation of a "clear and unambiguous" provision in a court order, *Harris,* 47 F.3d at 1348, and there is no such clarity here. Second, Bayer has "substantially complied"

with the consent decree by faithfully following the existing standard stated in the FTC's guidance, and a party who "substantially complies" with a court order cannot be held in contempt, *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 591 (3d Cir. 2010).

A. There Is No Clear And Convincing Evidence Of A Violation Of A Clear And Unambiguous Court Order.

To prove contempt, the government must show by clear and convincing evidence that Bayer violated a "clear and unambiguous provision of the consent decree." *Harris,* 47 F.3d at 1348. If there is any ambiguity or doubt, there can be no contempt. *Ford v. Kammerer*, 450 F.2d 279, 280 (3d Cir. 1971) (per curiam). A court "must not strain the decree's precise terms or impose other terms" not embodied in the agreement. *Harris v. City of Phila.*, 137 F.3d 209, 212 (3d Cir. 1998) (citing *United States v. Armour & Co.*, 402 U.S. 673, 681-82 (1971)). If the purported legal requirement cannot be "discern[ed]" from the "four corners" of the consent decree, the contempt action fails. *Id.*

The government cannot satisfy this standard. The government's clinical study design is found nowhere within the "four corners" of the consent decree, but only within the four corners of an expert report that was filed with the government's motion. *See also Garden of Life*, 845 F. Supp. 2d at 1335; *Basic Research*, No. 2:09-cv-0779. The consent decree speaks only of "competent and reliable scientific evidence" and defines it word-for-word identically with the FTC's Guidance (with the exception of a typographical error). Government's Response To Requests For Admission No.

1. That phrase does not "clear[ly] and unambiguous[ly]" require drug-level clinical trials; in fact, it does not require such trials at all. *See also Garden of Life*, 845 F. Supp. 2d at 1335-37; *Basic Research*, No. No. 2:09-cv-0779 at 26-27.

Further, if the government's test was clearly and unambiguously the standard, one would expect that one of Bayer's competitors would be meeting the standard. But no one does, even though virtually all of Bayer's competitors make similar probiotic claims. Merenstein Dec. at 11. Moreover, Dr. Laine testified that his test should apply beyond probiotics. Laine Tr. 229:15-21; Laine Tr. at 128:8-10. In its discovery requests, Bayer asked the government to identify which companies satisfy that test for any dietary supplement claim. The government could identify no one. *See* Government's Response to Interrogatory No. 4; *see also* Merenstein Dec. at 11 ("I am unaware of any probiotic that meets Dr. Laine's standard."); Fennerty Dec. at 5 ("If the government were correct, then no probiotic could be advertised by companies as effective because no probiotic that I know of meets this standard."); Blumberg Dec. at 13 ("If Dr. Laine's drug-level RCT criteria became the law, it would effectively remove almost all of the existing dietary supplements with structure/function claims from the market.").

The remainder of the government's discovery responses further confirms that the purported requirement was not "clear and unambiguous." Bayer asked the government to identify all occasions when the United States publicly asserted that "competent and reliable scientific evidence" requires clinical trials meeting Dr. Laine's

study design. In its response, the government identified no regulations, no guidance documents, and nothing else informing the industry that the standard probiotic claims that virtually everyone is making require drug-level clinical trials. *See* Government's Response to Interrogatory No. 2.

Instead, the government produced two charts, which supposedly "lists [sic] instances where Plaintiff has asserted with varying degrees of specificity the need for a randomized clinical trial to support a performance, benefits or efficacy claim relating to dietary supplements." Government's Interrogatory Response at 9. Nothing on the charts supports the government's position.

First, most of the items on the charts are *not even in the public domain*. We asked the Department of Justice for the non-public documents, and it refused to produce them, claiming it does not have them and did not review them. Dkt. No. 66 at 2. Supposedly, the information was not even "readily available" to the FTC. *Id.* at 2-3. Bayer cannot be held in contempt based on statements made in documents that are so obscure the government cannot even locate them. Accordingly, the government has since disclaimed reliance on these documents, Dkt. No. 70.

Second, virtually all of the rest of the documents on the chart were either (a) speeches by FTC staff attorneys who said they were *not* expressing the views of the government, but only their personal views, *see, e.g.*, Richard Cleland Speech at New York Academy of Science ("My comments reflect my own views and do not necessarily reflect the views of the Commission or any individual Commissioner."), or

(b) consent decrees with other companies. *See* Government's Chart No. 2. By definition, the personal views of agency attorneys do not impose any requirements on industry. The government's insinuation otherwise only underscores its desperation.

Likewise, the consent decrees lend the government no support. First, agreements with private parties do not bind the rest of the industry; by their terms, they apply only to the parties signing the agreement. Second, these consent decrees show that the FTC understands the difference between a clinical trial requirement and a "competent and reliable scientific evidence" requirement. The cited decrees contain both requirements. They expressly require clinical trials (though not with all of Dr. Laine's requirements) for particular claims (mostly disease claims and weight-loss claims), and then provide that other health-related claims require merely "competent and reliable scientific evidence," defined in much the same way as in Bayer's decree. Thus, when the government wants to require clinical trials, it knows how to do so. *See also In the Matter of Schering Corp.*, 118 F.T.C. 1030 (1994) (imposing two different requirements, one which defined "competent and reliable scientific evidence" similar to the definition in the agency guidance and Bayer's consent decree, and the other which applied only to weight-loss claims and had a *separate* definition, specifically requiring human clinical trials).

Finally, the remainder of the items on the charts further undermines the government's position. The government cites: (a) documents in cases in which the FTC was challenging *disease* claims, which are not covered by DSHEA, 21 U.S.C.

§ 343(r)(6) (*see, e.g.,* Complaint in *FTC v. Liverite Products*, Inc., No. 01-778 (C.D. Cal. Aug. 21, 2001), (b) court decisions in a case involving weight-loss claims in which the level of substantiation was not disputed and the defendants argued only that they did not make the claims at issue (*see, e.g., FTC v. Natl. Urological Group, Inc.*, 645 F. Supp.2d 1167, 1202 & n.21 (N.D. Ga. 2008)); (c) court decisions in the *Lane Labs* litigation, none of which construed "competent and reliable scientific evidence" to require clinical trials, (*see Lane Labs-USA, Inc.*, 624 F.3d at 578; *FTC v. Lane Labs-USA, Inc.*, No. 2:00-cv-03174, 2011 WL 5828518 (D.N.J. Nov. 18, 2011); and (d) three speeches noting that some of the recent consent decrees have expressly required clinical trials. *See* Hyperlinked Chart No. 2 (Duffy Cert. Exhibit I) (rows 2, 6, and 7).

One of these speeches, by Commissioner Edith Ramirez, is particularly telling. *See* Keynote Address of Commissioner Edith Ramirez, Association of National Advertisers Advertising Law & Public Policy Conference 1 (May 15, 2011) (speaking on behalf of herself, not the Commission). She explained that the FTC has started requiring clinical trials in consent decrees because "[t]he broad 'competent and reliable scientific evidence' standard found in the FTC's old orders *presented significant enforcement challenges*." *Id.* at 7 (emphasis added). "The Commission retooled its order provisions" to "provide brighter lines." *Id.* Unlike the "retooled" decrees, the Bayer decree contains no such lines requiring clinical trials.

The *most* that the FTC can say is that its prior enforcement actions have put the supplements industry on notice that disease claims and weight-loss claims require

clinical evidence of some kind (though not necessarily the drug-level trials the government is now seeking). By no means, however, can the agency legitimately contend that it had been "clear and unambiguous" in requiring drug-level clinical trials for ordinary structure/function claims in general or probiotic claims in particular. That explains why no one in the industry has conducted such trials even though Bayer's probiotic claims are commonplace.

If the FTC wants to impose a new standard on Bayer, it needs to revoke its existing guidance and promulgate a new standard for the industry. To do that, at the very least, the agency needs to conduct notice and comment rulemaking. What it cannot do is introduce a standard through a purported expert in a contempt action—especially when he admits he is not an expert in that supplement or any supplement. Because the government's test was not "clear and unambiguous," Bayer cannot be held in contempt. Not only would a contempt holding violate basic principles of contempt law, it would violate Due Process. *See*, *e.g., FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2318 (2012) (holding that Federal Communications Commission had violated due process by changing its "fleeting expletives" policy and finding, without fair notice, that two television networks had violated the new policy).

B. Bayer Has Substantially Complied With The Consent Decree, So It Cannot Be Held In Contempt.

Under Third Circuit precedent, a party cannot be held in contempt when it "substantially complies" with a court order. *Lane Labs*, 624 F.3d at 591. "A party

substantially complies when it takes all reasonable steps to do so, but nonetheless contravenes the court order by good faith mistake or excusable oversight." *Id.* at 590. "In order to avail oneself of the defense, a party must show that it (1) has taken all reasonable steps to comply with the valid court order, and (2) has violated the order in a manner that is merely 'technical' or 'inadvertent.'" *Id.* at 591.

There is no question that Bayer substantially complied. First, it fully complied with the published guidance. The only "standard" it failed to meet was the drug-level test that was announced for the first time in the filing of this complaint on September 12, 2014. Bayer did not comply with this test because it was not articulated during—or at any time preceding—the government's "prolonged delay in initiating contempt proceedings." *Id.* at 591 n.19. *See also FTC v. Lane Labs-USA*, 2011 WL 5828518, at *10 (D.N.J. Nov. 18, 2011) ("This extensive delay understandably led Defendants to believe that they were in compliance with the Final Order, and for the FTC to bring its motion after six years seems to the Court to be fundamentally unfair."); *Precious Metals Assocs. v. Commodity Futures Trading Comm'n.*, 620 F.2d 900, 909 (1st Cir. 1980) (noting that courts have applied laches "where unreasonable agency delay has caused hardship.").

Second, any violation was "inadvertent." Bayer did all it could and simply did not know the standard, which did not yet exist. Bayer filed multiple notification letters with the FDA, beginning on July 8, 2008, disclosing its dietary supplement claims to the government. Yet, for years, the government never objected to these

claims, and never even issued a warning letter, which would have put Bayer on notice of the purported violation. Nor to this day has the government issued warning letters in response to over 100 other notifications by other companies making similar claims. *See, e.g.*, Notification Letter from Jeffrey Bram, Garden of Life, to FDA (Jan. 4, 2013) ("helps relieve the occasional symptoms of gas, bloating, constipation and diarrhea"); Notification Letter from Brian Spurling, Good Herbs, to FDA (Nov. 24, 2010 ("for relief from occasional constipation"). Instead, it jumped headlong into a contempt action, wielding a new standard and seeking "hundreds of millions" of dollars in contempt damages, Dkt. No. 4 Attachment 1 at 29-30; *see United States v. Atl. Ref. Co.*, 360 U.S. 19, 23 (1959) (rejecting government's attempt to change interpretation of consent decree when "the language . . . in its normal meaning supports [a different] interpretation" that the "[g]overnment accepted . . . without challenge" for years).

Finally, any violation was "technical" (although it need not be for application of "substantial compliance," which is phrased in the disjunctive: "inadvertent *or* technical"). According to the government, the standard turns on a single purported expert's opinion on a matter of emerging science regarding the balance of trillions of microorganisms in the gut. It is hard to imagine what could be more "technical."

CONCLUSION

The Court should reject the government's attempt to hold Bayer in contempt.

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